Biotech Daily

Tuesday December 13, 2022

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: AVITA UP 7%; DIMERIX DOWN 6%**

*** $230k VICTORIA PRIZES FOR SCIENCE & INNOVATION, FELLOWSHIPS**

*** FTI: HOUGH TO PAY $56m FOR ELLUME**

*** NEXT SCIENCE $10m WALKER GROUP CONVERTIBLE NOTES**

*** PACIFIC EDGE: BIOMARKERS 'SIGNIFICANTLY IMPROVE' CXBLADDER**

*** STARPHARMA AZD0466 'SAFE, NO DOSE LIMITING TOXICITIES'**

*** DIMERIX DMX-200 'SAFE, WELL-TOLERATED FOR COVID-19'**

*** INOVIQ EXO-NET '90% ACCURATE FOR EARLY OVARIAN CANCER'**

*** RADIOPHARM RAD201 'PROMISING NON-INVASIVE TOOL' FOR CANCER**

*** QUEENSLAND UNI ULTRASOUND FOR ALZHEIMER'S SAFETY TRIAL**

*** AVITA AGM 24.9% OPPOSE DIRECTOR OPTIONS**

*** NANOSONICS PLEADS SCHULTZ TO ASX 14% FALL QUERY**

*** KAZIA BELOW NASDAQ $US1 BID RULE**

*** CSL: DR PAUL MCKENZIE TO REPLACE M-D PAUL PERREAULT, ON $2.6m PA**

*** TRUDELL TAKES 22% OF ADHERIUM**

*** UNIVERSITY OF WESTERN AUSTRALIA BELOW 5% IN ARGENICA**

*** CEO DR ANDREW RONCHI BELOW 5% IN DORSAVI**

MARKET REPORT

The Australian stock market was up 0.31 percent on Tuesday December 13, 2022, with the ASX200 up 22.5 points to 7,203.3 points. Sixteen of the Biotech Daily Top 40 stocks were up, 15 fell, six traded unchanged and three were untraded.

Avita was the best, up 14.5 cents or 7.4 percent to $2.10, with 504,742 shares traded. Imugene improved 5.4 percent; Nanosonics, Oncosil, Pharmaxis, Polynovo, Prescient, Starpharma and Telix climbed four percent or more; Mesoblast, Neuren and Paradigm were up more than three percent; Actinogen, Antisense, Cochlear, Genetic Signatures and Orthocell rose more than one percent; with Resmed up by 0.15 percent.

Dimerix led the falls, down one cent or 6.1 percent to 15.5 cents, with 34,367 shares traded. Cynata fell 4.9 percent; Proteomics and Resonance lost more than three percent; Clinuvel, Immutep, Impedimed, Kazia, Pro Medicus and Volpara shed two percent or more; Atomo, Cyclopharm and Next Science were down more than one percent; with CSL, Medical Developments and Opthea down by less than one percent.

VICTORIA GOVERNMENT

The Victoria Government says that four scientists will share the $50,000 Victoria Prize for Science and Innovation in Life Sciences.
A State Government spokesperson told Biotech Daily that Monash University's Prof Joshua Ooi and Prof Eric Morand would receive $25,000 for work that could lead to therapies to treat autoimmune diseases such as rheumatoid arthritis.
The spokesperson said that La Trobe University's Prof Brian Abbey and the Peter MacCallum Cancer Centre's Prof Belinda Parker would receive $25,000 for the use of nanotechnology and microscope slides to rapidly detects cancer cells.
A Government media release said 10 Fellowships worth up to $18,000 each were awarded with details at: www.veski.org.au/victoria-prize-fellowships.

ELLUME (IN ADMINISTRATION)

FTI Consulting says that the Burleigh West, Gold Coast, Queensland-based Hough Consolidated Pty Ltd has proposed to buy Ellume for $US38 million ($A56.2 million).
FTI said that it supported the Hough proposed deed of company arrangement (DOCA) to buy Ellume and provide funding to enable ongoing operations, which was expected to be decided at a second creditors meeting on December 20, 2022.
In September Ellume's voluntary administrators, FTI Consulting, said the company has $140 million in liabilities, its US business was not subject to the voluntary administration and would continue to trade as business as usual and FTI would continue to operate the Australian business on a "business as usual" basis to either recapitalize via a deed of company arrangement or going concern sale (BD: Sep 1, 13, 2022).
Last year, Ellume recalled "specific product lots of [severe acute respiratory syndrome coronavirus-2] tests" after they reported false positive test result rates higher than was observed in clinical testing having previously said the US Government would provide $US231.8 million ($A302.8 million) to produce the home tests (BD: Feb 2, Oct 7, 2021).
Yesterday, in its 'Report to creditors' FTI said that "reasons for the company's failure" included the recall of the Covid-19 home test, a "material change in demand … [for the test] following the release of free [rapid antigen tests] … by the US government", substantial upfront capital expenditure in readiness for long-term expansion, funding issues and "unfavorable capital market conditions".
The administrators said Hough Consolidated Pty Ltd had proposed a deed of company arrangement to buy Ellume for $US38 million ($A56.2 million) and provide funding to enable ongoing operations, which was expected to be completed by March 10, 2023.
FTI said that "a key aspect of the DOCA is the transfer of 100 percent of shares … to Hough … [and] does not provide for any consideration to be paid to current shareholders".
FTI said that under the deed, secured and priority creditors would receive all their funds owed, Qiagen would receive 47 percent, small claim creditors would receive 50 percent, noteholders would receive between 15 and 35 cents in the dollar, with other unsecured creditors receiving between nothing and 20 percent.
FTI said that if the company was liquidated then the secured creditors would receive up to 24 percent of the money owed to them and all others would receive nothing.
The administrators said that the second creditors meeting to decide the deed proposals was due to be held on December 20, 2022 at 2pm (AEST).
Hough's website says it provides home tests for menopause, pregnancy, ovulation, vitamin D, urinary tract infections and iron levels, with tests for Covid-19, fertility, women's health, blood sugar, sexually transmitted infections and "vital health" all "coming soon".
Ellume is a public unlisted company.

NEXT SCIENCE

Next Science says it has a $10,000,000 convertible notes deed with 38.90 percent shareholder Walker Group Holdings Pty Ltd, pending shareholder approval.
In July, Walker Group and Auckland Trust Co said they had increased and been diluted in Next Science from 76,072,938 shares (39.53%) to 83,547,061 shares (38.90%).
Today, Next Science said the note had a conversion price of 72 cents a share, with a 10 percent interest rate per annum if the notes were redeemed or a five percent interest rate per annum if the notes were converted.
Next Science fell one cent or 1.45 percent to 68 cents.

PACIFIC EDGE

Pacific Edge says an 804-patient study has shown its Cxbladder tests had “significant improvements” from the addition of DNA biomarkers.
Pacific Edge said the study showed “an improvement in all performance characteristics” over the existing versions of the Cxbladder Triage and Cxbladder Detect products for the detection and management of bladder cancer.
The company said there was a 23 percent improvement to 97 percent sensitivity and an eight percent improvement to 90 percent specificity, for Cxbladder Detect+.
Pacific Edge said the study, titled ‘Urinary Analysis of FGFR3 and TERT Gene Mutations Enhances Performance of Cxbladder Tests and Improves Patient Risk Stratification’ was published in the American Urological Association Journal of Urology.
Pacific Edge chief executive officer Dr Peter Meintjes said “by adding DNA biomarkers, we have developed Cxbladder Detect+ a single product for haematuria evaluation that can assist clinicians to safely and reliably rule in or rule out the presence of bladder cancer for any haematuria patient at any point in the patient care pathway”.
“Detect+ will require its own coding, coverage and pricing decisions to ultimately establish reimbursement however, given the increased performance it could potentially receive a higher price,” Dr Meintjes said.
Pacific Edge was untraded at 41.5 cents.

STARPHARMA HOLDINGS

Starpharma says Astrazeneca data shows that AZD0466 with its dendrimer enhanced product (DEP) has no dose-limiting toxicities and is safe and well-tolerated.
Starpharma said AZD0466 was a “highly optimised dendrimer nanoparticle formulation of an Astrazeneca drug” using its technology to improve solubility, efficacy, pharmaco-kinetics, targeting and reduce toxicities.
In 2020, the company said it had received a $US3 million ($A4.48 million) milestone payment from Astrazeneca following the dosing of the first patient in a phase I ASD0466 trial, which began December (BD: Jan 19, Feb 11, 2020).
Today, Starpharma said there had been no discontinuations due to adverse events, five dose escalations had been completed, with further escalations underway.
Starpharma said that the data from the ongoing phase I/II trial in patients with advanced relapsed or refractory leukemia was presented by Astrazeneca at the American Society of Hematology annual meeting in New Orleans, Louisiana.
Starpharma chief executive officer Dr Jackie Fairley said that AZD0466 was “the result of a highly successful collaboration … and the presentation of this trial data marks an important milestone in the development of AZD0466”.
Starpharma was up two cents or four percent to 52.5 cents.

DIMERIX

Dimerix says its 49-patient, Clarity 2.0 study of DMX-200 for Covid-19 shows it is generally safe and well-tolerated.
Dimerix said that “92 percent” (45 of the 49 participants” receiving either DMX-200 or placebo did not require hospitalization and had no limitation on activities at day-14.
The company said that, coincidentally, the same percentage had prior vaccination.
Last year, Dimerix said that Clarity 2.0 was an investigator-led, prospective, randomized, double blind, placebo-controlled study and the primary endpoint would be an eight-point clinical health score measured on treatment day-14, with participants treated for up to 28 days, with longer term outcomes assessed at 26 weeks (BD: Oct 15, 2021).
In August, Dimerix said the study had concluded recruitment at 49 participants rather than the intended 80 patients “given additional patient recruitment would likely not change... safety and efficacy” (BD: Aug 18, 2022).
Today, Dimerix said that 25 patients received DMX-200 and 24 received a placebo for 28 days, as well as with an angiotensin receptor blocker, and that the study found that DMX-200 was safe and well-tolerated, with no serious adverse events.
The company said the cohort was “low risk, highly vaccinated and with high rates of other Covid-19 treatments” and 69 percent had received concomitant cortico-steroid treatment.
Dimerix said that at day-14, 92 percent of all patients did not require hospitalization and had no limitation on activities, with four percent not hospitalized but with limited activity.
Dimerix said the median time to oxygen free status was four days in the DMX-200 group and five days in the placebo group, median hospital stay was six days in both groups, with the study was halted early in part due to falling rates of Covid-19 hospitalizations.
Dimerix managing-director Dr Nina Webster said that further data from the trial including the six-month follow-up was expected “early next year”.
Dimerix fell one cent or 6.1 percent to 15.5 cents.

INOVIQ

Inovq says a University of Queensland study of 97 plasma samples shows its Exo-Net is more than 90 percent accurate for the detection of early-state ovarian cancer.
In April, Inoviq said it would expand its exosome-based ovarian cancer screening test development program with the University of Queensland, who would further evaluate its Exo-Net isolation technology to develop an ovarian cancer test (BD: Apr 1, 2022).
At that time, the company said that exosomes were present in fluids such as blood, urine and saliva, and contained DNA, RNA, proteins and lipids that could be used for the identification of biomarkers, diagnosis and treatment of disease.
Today, Inoviq said that Exo-Net was used to isolate extracellular vesicle biomarkers from plasma obtained from women with early-stage ovarian cancer, benign ovarian masses and normal healthy women, and found that 27 extracellular vesicle biomarkers were “highly informative ($p < 0.0001$) of early-stage … ovarian cancer”.
The company said that when selected biomarkers were combined in a multi-variate algorithm, a high-performing, cross-validated classification model was generated with an area under the curve of greater than 0.98, sensitivity greater than 0.92, specificity greater than 0.92 and a 92 percent rate of correct cancer identification.
Inoviq chief executive officer Dr Leearne Hinch said the study was “the first milestone achieved in the collaboration with the University of Queensland to develop a world-first [extracellular vesicle] ovarian cancer screening test”.
Inoviq was up 13 cents or 21.3 percent to 74 cents with 1.3 million shares traded.

RADIOPHARM THERANOSTICS

Radiopharm says a six-patient study shows its HER-2 nanobody, RAD201, is a “promising non-invasive tool for discriminating HER-2 status in metastatic, breast, cancer”.

Radiopharm said that the study treated six human epidermal growth factor receptor-2 (HER-2) positive, heavily pre-treated patients with different cancer types, who were administered with 500 mL of Gelofusine solution for radiation protection before the tracer injection, and found that RAD201 was safe, had a favorable bio-distribution, showed high accumulation in all active HER-2 positive tumor sites and a high target-to-background ratio, favorable tumor targeting and rapid blood clearance.

The company said that RAD201 was a promising non-invasive tool for discriminating HER-2 status in metastatic cancer, regardless of ongoing HER-2-targeted antibody treatment due to its ability to bind to a different part of the HER-2 receptor.

Radiopharm said that the study, titled ‘99mTc-labeled single-domain antibody for SPECT/CT assessment of HER2 expression in diverse cancer types’ was published in the European Journal of Nuclear Medicine & Molecular Imaging, with the full article available at: https://link.springer.com/article/10.1007/s00259-022-06066-3.

Radiopharm managing-director Riccardo Canevari said the study was “an outstanding endorsement of our RAD201 technology that gives us added confidence to develop this asset even further”.

“HER-2 positive breast cancer is around 15 to -20 percent of all breast cancer cases, is particularly aggressive and hence has a higher mortality rate... [and] any new imaging or therapeutic solutions that can make a difference for this disease are highly sought after,” Mr Canevari said.

Radiopharm fell one cent or 9.1 percent to 10 cents with 1.8 million shares traded.

THE UNIVERSITY OF QUEENSLAND, QUEENSLAND GOVERNMENT

The University of Queensland says it has begun a 12-patient, 12-month safety trial of its ultrasound device to treat Alzheimer’s disease and restore memory functions.

In a media release, the University said that the trial would be conducted at the Mater Hospital Brisbane, led by Queensland Brain Institute’s Prof Jürgen Götz with Prof Peter Nestor.

Prof Götz said that the study followed a 2015 discovery “that ultrasound could clear the toxic amyloid-beta plaque build-up, the hallmark of Alzheimer’s disease and … restore memory functions”.

Prof Götz said the study would determine whether the ultrasound could be safely delivered.

“There is currently no effective treatment for Alzheimer’s, so it is hugely rewarding that we could in the future potentially treat the disease with ultrasound,” Prof Götz said.

Prof Nestor said “we’re treating an area at the back of the brain that is affected early in the course of Alzheimer’s disease”.

“Each participant receives four treatments which will be administered fortnightly, and after completing the course, they’ll have [a magnetic resonance imaging] scan of the brain and a repeat cognitive test,” Prof Nestor said.

In the media release, Queensland Minister for Innovation Stirling Hinchliffe said the State Government had invested $5 million into the University of Queensland’s Brain Institute to develop and trial the prototype ultrasound device for treating dementia.

“The safety trial starting now brings [the Queensland Brain Institute] one step closer to a potential world dementia treatment breakthrough, made and developed in Queensland,” Mr Hinchliffe said.

AVITA MEDICAL

Avita says its annual general meeting voted up to 24.99 percent against the issue of restricted stock units and options to five directors.

Avita said that the largest dissent was against the issue of $US87,500 ($A129,420) worth of restricted stock units and $US37,500 worth of options to director Jeremy Curnock Cook, which faced 2,745,543 votes (24.99%) against and 7,612,792 votes (69.31%) in favor.

The company said that resolutions to issue the same amount of restricted stock units and options each to directors Lou Panaccio, Suzanne Crowe, Jan Stern Reed and chief executive officer James Corbett faced opposition ranging from 17.02 to 24.90 percent.

Avita said that an advisory vote on the company's compensation of executive officers had 2,381,954 votes (21.68%) against and 7,832,181 votes (71.30%) in favor.

The company said that the resolution to amend its bylaws to reduce the quorum requirement for meetings from a majority of outstanding votes to one third of outstanding votes was lost, with 956,344 votes (8.71%) against the resolution and 9,587,285 votes (87.27%) in favor.

Avita said that the resolution "was not carried as the number of votes required to approve the proposal was not reached".

The company said that all other resolutions passed easily.

According to its most recent filing, Avita had the equivalent of 12,590,451 US shares on offer, meaning the votes against the issue of stock to Mr Curnock Cook amounted to 21.8 percent of the company, sufficient to requisition extraordinary meetings, if it was an Australian company.

Avita was up 14.5 cents or 7.4 percent to $2.10 with 504,742 shares traded.

NANOSONICS

Nanosonics has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

In the query, the ASX said that the company's share price fell 66 cents, or 13.6 percent from a high of $4.84 on close of trading December 9, 2022, to an intraday low of $4.18 on December 12, 2022, but did not note an increase in trading volume.

Nanosonics was up 19 cents or 4.4 percent to $4.55 with 1.3 million shares traded.

KAZIA THERAPEUTICS

Kazia says it has received a non-compliance letter from the Nasdaq requiring it to ensure its share price is above $US1.00 within 180 days.

Kazia said that based on the closing bid price of its American depository shares, each representing 10 Australia shares, for the period from October 27, 2022 to December, 8 2022, the company no longer met the requirement to maintain a minimum bid price of at least $US1.00 per share.

The company said that it had until June 7, 2023 to regain compliance, with the minimum bid price at or above $US1.00 for 10 consecutive business days.

Kazia said the notice only applied to the Nasdaq and not shares trading on the ASX.

Kazia fell 0.2 cents or 2.1 percent to 9.3 cents.

CSL

CSL says chief operating officer Dr Paul McKenzie has been appointed a directors and will replace managing-director Paul Perreault, from March 6, 2023.
The company said that former CSL Behring president Mr Perreault had been appointed chief executive officer and managing-director from July 2013 (BD: Aug 3, 2012).
Today, CSL thanked Mr Perreault for his leadership since 2013 and more than 25 years with CSL and said he would assist with the transition until he retired in September 2023.
CSL said the Pennsylvania-based Dr McKenzie had more than 30 years' experience in the biotechnology industry, including at CSL as chief operating officer since 2019.
The company said that prior to joining the company, Dr McKenzie worked for Biogen as head of pharmaceutical operations and technology, as well as Johnson and Johnson, Bristol-Myers Squibb and Merck and had been a company director.
CSL said Dr McKenzie held a Bachelor of Science from the University of Pennsylvania in Philadelphia and a Doctor of Philosophy from Carnegie Mellon University in Pittsburgh.
The company said that Dr McKenzie would be paid a base rate of $US1,750,000 ($A2,590,000) a year, with a short-term incentive of 120 percent of his fixed remuneration, and a long-term incentive maximum opportunity of 425 percent of his fixed remuneration.
CSL chair Dr Brian McNamee said the company acknowledges "the remarkable leadership of Paul Perreault as [chief executive officer] for 10 years".
"With Paul at the helm, CSL delivered sustainable growth and innovation with a patient-focused culture," Dr McNamee said.
"Thanks to Paul's leadership, CSL today has grown to become a global leader, delivering shareholder value and industry-leading life-saving medicines to people in more than 100 countries," Dr McNamee said.
"In working closely with Dr McKenzie for more than three years, I am confident he will continue to innovate and build on CSL's track record of growth for years to come," Mr Perreault said.
CSL fell $1.16 or 0.4 percent to $297.04 with 653,623 shares traded.

ADHERIUM

Trudell Medical says it has increased its substantial holding in Adherium from 950,580,272 shares (19.91%) to 1,103,080,272 shares (22.15%).
The London, Ontario-based Trudell said that it participated in a placement on December 12, 2022, buying 152,500,000 shares for $762,500 or 0.5 cents a share.
In September, Adherium said it had "commitments" for $13.5 million in a placement at 0.5 cents a share (BD: Sep 16, 2022).
Adherium was unchanged at 0.4 cents.

ARGENICA THERAPEUTICS

The University of Western Australia says its 3,953,000 share-holding in Argenica has been diluted below the five percent substantial level. ion of its votes
The University said its holdings were diluted as a result of a placement on June 10, 2022.
In June, Argenica said it had binding commitments for $5.5 million in an institutional placement at 40 cents a share (BD: Jun 3, 2022).
According to its most recent filing Argenica had 64,296,498 shares on issue with 22,625,752 shares in ASX escrow and Biotech Daily calculates the University retains 4.55 percent of Argenica.
Argenica fell three cents or 6.1 percent to 46 cents.

DORSAVI

Chief executive officer Dr Andrew Ronchi says that through the Tanarny Super Fund, he has been diluted below the five percent substantial level.

In July, Dr Ronchi said that through the Tanarny Super Fund he had become substantial in Dorsavi with 19,915,656 shares or 5.59 percent (BD: Jul 1, 2022).

Today, the Melbourne-based Dr Ronchi said that he was diluted due to the issue of 38,500,000 shares on conversion of convertible notes on December 6, 2022.

Dorsavi was untraded at 1.2 cents.